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| 10/518,056   | 10/03/2005  | Per-Ola Freskgard    | FRESKGARD8          | 8250                 |
| 1444   | 7590        | 05/27/2009           | EXAMINER            |                      |
| BROWDY AND NEIMARK, P.L.L.C.<br>624 NINTH STREET, NW<br>SUITE 300<br>WASHINGTON, DC 20001-5303 |             |                      |                     | BABIC, CHRISTOPHER M |
| ART UNIT   |             | PAPER NUMBER         |                     |                      |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/518,056             | FRESKGARD ET AL.    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | CHRISTOPHER M. BABIC   | 1637                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on February 17, 2009.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-5,7-9,12,15,16,18,19,21-23 and 25-38 is/are pending in the application.

4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-5,7,12,15,16,18,19,21-23 and 25-38 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Status of the Claims***

Claim(s) 1-5, 7-9, 12, 15, 16, 18, 19, 21-23, and 25-38 are pending. Claim(s) 1-5, 7, 12, 15, 16, 18, 19, 21-23, and 25-38 are under examination. The following Office Action is in response to Applicant's communication dated February 17, 2009.

***Specification***

The objection to the specification has been withdrawn in view of Applicant's amendments.

***Claim Objections - Withdrawn***

Applicant's claim amendments and/or supplemental remarks are sufficient to overcome the objection of claim(s) 1-7 and 11-24 presented in the Office Action dated October 8, 2008.

***Claim Rejections - 35 USC § 112 - Indefiniteness - Withdrawn***

Applicant's claim amendments and supplemental remarks (see pg. 13-14) are sufficient to overcome the rejection of claim(s) 1-7 and 11-124 presented in the Office Action dated October 8, 2008.

***Claim Rejections - 35 USC § 112 - Indefiniteness***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 2-5, 12, 15, 16, 19, 25, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The above claims are indefinite because it is unclear whether the claimed invention is directed to a method or an apparatus. In other words, it is unclear how the recited method steps limit the claimed product. In the instant case, the claimed "microarray" recites the steps "each encoded molecule is obtained" and "microarray is obtained."

In support of the examiner's position, Applicant is directed to a recent Federal Circuit decision, *IPXL Holdings, LLC v. Amazon.com, Inc.*, 333 F. Supp. 2d 513 (E.D. Va. 2004), which the Federal Circuit affirmed in part, 2005 U.S. App. LEXIS 25120, where after upholding the district court's claim constructions and affirming the finding that all but one of the asserted claims were anticipated, the Federal Circuit next affirmed the summary judgment of invalidity (for indefiniteness) for the remaining asserted claim, which read:

25. The system of claim 2 [including an input means] wherein the predicted transaction information comprises both a transaction type and transaction parameters associated with that transaction type, and the user uses the input

means to either change the predicted transaction information or accept the displayed transaction type and transaction parameters.

Claim 25 on its face is directed to a "system." However, it also recites use steps ("the user uses the input means to ...change the predicted transaction information ... ") This claim was found indefinite by the district court.

***Claim Rejections - 35 USC § 112 - New Matter - Withdrawn***

Applicant's arguments (see remarks pg. 14-16) have been fully considered and are persuasive. Thus, the rejection has been withdrawn.

***Claim Rejections - 35 USC § 102 - Withdrawn***

Applicant's claim amendments and supplemental remarks are sufficient to overcome the rejection of claims 1-7 and 11-24 over Polsky-Cynkin and the rejection of claims 1-6, 11-14, 16, 17, 20, 22, and 24 over Szostak. Thus, the rejection has been withdrawn.

***Claim Rejections - 35 USC § 102 - New Grounds***

The following rejection(s) are made in view of Applicant's amendments.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-5, 12, 15, 16, 19, 25-33, and 35- 38 are rejected under 35**

**U.S.C. 102(b) as being anticipated by Winzeler et al. (Methods Enzymol. 1999;306:3-18) as evidenced by Fegan et al. (Chem Commun (Camb). 2008 May 7;(17):2004-6).**

Upon review of the amended claim language, it is submitted that the claimed product reads on the product of the well known prior art method of fluorescent microarray analysis. Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim (see MPEP 2111.02, for example).

With regard to claims 1, 22, 23, 26-33, and 38, for example, Winzeler teaches the production of a microarray (fig. 1, for example) comprising immobilized single-stranded DNA probes (pg. 5-6, oligonucleotide microarrays, less than 50 bases) hybridized to fluorescently labeled cDNA probes (pg. 5, nucleic acid probes 500 bases; pg. 12, table III, Cy3 label). In this case, the labeled cDNA probes act as "complexes" as recited in the claimed invention since the cyanine dyes (Cy3 and Cy5) act as "encoded molecules" that comprise a plurality of "structural units" that do make a nucleic acid molecule. In support of this interpretation, the following structure of the cyanine 3 chemical structure taken from Fegan, is submitted:

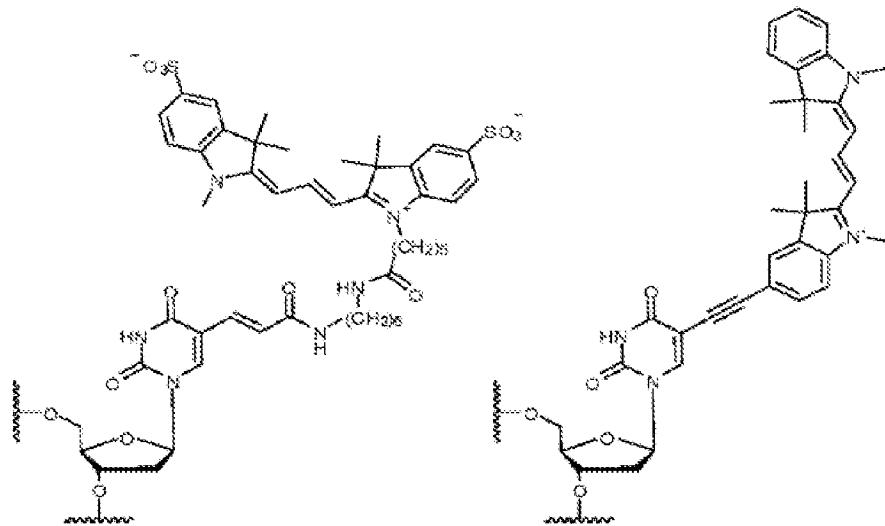


Fig. 1 Attachment of a Cy3 dye to DNA via a common flexible linker (left) and a rigid ethynyl linker (right).

With regard to figure 1 above, the "template" is the DNA (sugar and base) and the "structural units" can be anyone of the 5 or 6 member rings as well as carbon linkages between such rings. Thus, given that the "encoding" function of the probe and template molecules is an intended use, one can think of the individual nucleotide bases of A, T, C, G, or virtually any combination of the bases (e.g. a base triplet) of the genes (see Kahn, fig. 10, for example) as coding for a structural unit of the fluorescent molecule.

With regard to claims 2-5, 12, 15, 16, 19, 25, and 37, due to the indefiniteness of the claimed language (see section 112, 2nd para) and the intended use recitation, the end product of Winzeler is thought to anticipate the claimed product.

With regard to claim 35 and 36, the terms "spacer sequence" and "priming sites" are intended uses of the claimed sequences taught by Winzeler.

***Claim Rejections - 35 USC § 103 - New Grounds***

The following rejection(s) are made in view of Applicant's amendments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**1. Claim(s) 1-5, 12, 16, 19, and 25-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szostak et al. (U.S. 6,207,446 B1) in view Schultz (WO 90/05785 A1; 31 May 1990).**

As noted by Applicant (specification pg. 1), Szostak teaches the general structure of claimed invention comprising: a plurality of single stranded nucleic acid probes

immobilized in discrete areas of a solid support, a library of complexes, templates, codons, and structural units (fig. 1-2; col. 42-44, microchips comprising RNA-Protein fusions, nucleic acid templates comprising codons and anticodons, for example).

Szostak does not expressly teach encoded molecules that are not composed solely of the 20 genetically encoded amino acids.

Schultz provides a supportive disclosure that teaches methods of *in vitro* incorporation of unnatural amino acids to produce novel proteins (pg. 2-5, D-phenylalanine, (s)-p-fluorophenylalanine, etc); pg. 34-46, experimental, for example). The reference also highlights that, "The physical and biochemical properties which can be studies by making substitutions at known and specific sites are many,..., The invention provides the opportunity to introduce into the polypeptide chemical groups which are beyond the range of natural amino acids, and to escape from many of the constraints previously imposed by nature" (pg. 29-30)."

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to utilize the methods of Schultz within Szostak since the prior art suggests such a combination to allow for incorporation of unnatural amino acids into proteins for among other reasons research purposes.

**2. Claims 7, 15, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szostak et al. (U.S. 6,207,446 B1) in view Schultz (WO 90/05785**

**A1; 31 May 1990) as applied to claims 1-3 and 25, and in further view of Felder et al. (U.S. 6,232,066 B1).**

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach hybridization to a solid support through an adapter oligonucleotide.

Felder teaches the use a microarray configuration that utilizes a linker oligonucleotide, i.e. an adaptor oligonucleotide, to attach target labeled mRNA molecules to the microarray (fig. 1,2; col. 3, for example). The references expressly teaches that the illustrated combination of anchor and linker oligonucleotides on the microarray configuration can allow the simultaneous detection of target mRNA from 15 different samples (col. 3, lines 40-50, for example).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a skilled artisan at the time of invention to utilize the microarray configuration according to Felder to detect the mRNA-protein fusion molecules according to Szostak since the prior suggests such a combination to allow for the simultaneous analysis of 15 different samples.

### ***Conclusion***

**No claims are allowed.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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